Metropolitan Life Insurance Company
One Madison Avenue
New York, NY 10010-3690

MetLife®

231445

February 16, 2000

U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Attention: Privacy -P
Room G-322A
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Assistant Secretary:

We are writing on behalf of Metropolitan Life Insurance Company in response to your Department's request for comments on proposed rule 45 CFR Parts 160 through 164, Standards for Privacy of Individually Identifiable Health Information. As requested, one original and three copies of our comments arc enclosed along with a 3½ inch floppy disk that contains an electronic version of the comments.

Our comments are divided into two sections: general comments and specific comments. Our general comments address two issues:

1. Applicability of the proposed rule to multi-line insurance companies such as MetLife;
2. Preemption of state laws.

Our specific comments relate to the following sections/topics:

1. Definitions-Sections 160.103 and 164.504;
2. Introduction to General Rules – Section 164.506;
3. Treatment, Payment, and Health Care Operations – Section 164.506;
4. Individual Authorization Section 164.508;
5. Uses and Disclosures Permitted Without Individual Authorization Section 164.510;
6. Notice of Information Practices Section 164.512; and
7. Relationship to Other Laws.

We trust these comments will be useful in your review of the proposed rule. We thank you for the opportunity to submit them and look forward to a continuing dialog with you on these issues

Very truly yours,

Michael F. Tietz
Vice-President
Institutional Business

Edmund G. Rakowski
Assistant Vice-President
Client Services

METROPOLITAN LIFE INSURANCE COMPANY
COMMENTS ON PROPOSED STANDARDS FOR PRIVACY OF INDIVIDUALLY INDENTIFIABLE HEALTH INFORMATION

February 17, 2000

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METROPOLITAN LIFE INSURANCE COMPANY
COMMENTS ON PROPOSED STANDARDS FOR PRIVACY OF INDIVIDUALLY INDENTIFIABLE HEALTH INFORMATION

Metropolitan Life Insurance Company ("MetLife") respectfully submits these comments on the Standards for Privacy of Individually Identifiable Health Information proposed by the Department of Health and Human Services ("HHS") on November 3, 1999 (the "Proposed Rule").[1] MetLife has a number of concerns, general and specific, regarding the Proposed Rule. Most fundamentally, we are concerned that the Proposed Rule (1) does not provide the information needed for businesses to adopt procedures to ensure compliance, (2) would be particularly onerous for the insurance industry in that it would increase costs, reduce efficiency and thereby make us less able to serve our policyholders, and (3) would impede insurer ability to detect and prevent insurance fraud. These and other serious concerns are reflected in our comments below.

I. GENERAL COMMENTS

A . Applicability

MetLife is a multi-line insurance company whose businesses sometimes involve the receipt of individually identifiable health information during the underwriting and claims processes. While certain products in such companies provide reimbursement for costs incurred for some forms of health care, other products do not. As a consequence, if one line of business or department of a company meets the definition of "covered entity" under the Proposed Rule, it is not clear whether the company would be deemed a covered entity for all purposes, or if the definition applies on a functional basis, i.e., only to a specific line of business or department, or on a transactional-specific basis, i.e., only to specific transactions.

As we understand the Proposed Rule, multi-line insurance companies such as MetLife would not be considered a covered entity for all purposes, across all lines of business. Rather, we read the Proposed Rule as defining multi-line insurance companies as "covered entities" on a functional basis, meaning that one or more specific lines of their business are "covered entities" while others are not. Because the Proposed Rule is ambiguous on this point, however, we urge clarification of the issue in the final version of the Rule.

Even if the definition of "covered entity" is satisfactorily clarified, the Proposed Rule presents potentially significant difficulties with respect to necessary transfers of medical information within a multi-line company. It is unclear, for example, whether a specific authorization would be required for intra-company disclosures, If this were required, would each line of business have to obtain a separate authorization? Any such

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[1] 64Fed. Reg. 59918 (1999).

requirement would significantly delay claims payments and increase insurers' administrative costs. Inevitably, these costs are passed on to the consumer.

For example, assume an individual has several insurance products with the same company: a life insurance policy with a disability waiver of premium provision, a disability income policy, and a long-term care policy. How could the three lines of business share information under the Proposed Rule? Such sharing is a necessary element of an insurer's business operations. For example, the information submitted in connection with a long-term care claim could be used to support and process claims under the claimant's disability income policy and life insurance policy's waiver provision, an efficient approach appreciated by the insurer's customers.

The underwriting process presents another example. Underwriting units of an insurance company routinely check applicants for insurance against a list of individuals who have previously applied for insurance with the company. In instances in which the company records indicate that an individual's application has been previously declined, or that the individual has obtained a rated policy, the underwriter may request additional information in support of the current application.

These are among the problems and questions regarding the applicability of the Proposed Rule that we have identified and addressed in the Specific Comments section below.

B . Preemption

A number of multi-line insurance companies such as MetLife insure policyholders in all of the 50 states, the District of Columbia, and the U.S. Commonwealths, territories and protectorates. Such insurers' business operations, including their practices with respect to the privacy of medical information, may be subject to the different laws of all these individual jurisdictions. Ensuring compliance with the details of all of these numerous, varying laws requires extensive monitoring and close attention – a considerable task.

The Proposed Rule, because it would not preempt "more stringent" state law, would add a layer of extraordinary complexity to the existing patchwork of state laws currently governing the privacy of medical information. We recognize that HHS is limited by Congress' decision that privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[2] would not preempt "more stringent" provisions of state medical information privacy law.[3] However, we have grave concerns, as expressed more fully in our Specific Comments below, regarding the mechanisms set forth in the Proposed Rule for determining whether a state law is in fact "more stringent" than the federal standards, As our comments suggest, we believe that the burdens of making such determinations, and ensuring compliance with both the

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[2] Pub. L. No. 104-91, 110 Stat. 1936 (1996).

[3] Id. § **264(c)(2).**

federal Rule and any state laws deemed to be "more stringent" within the meaning of HIPAA, will far outweigh the possible benefits of retaining the purportedly more protective state laws after the federal standards are adopted.

Given the HIPAA limitations on HHS's authority with respect to preemption in this context, we strongly urge HHS to impress upon Congress the need for legislation that would provide for national uniformity by directing that federal medical data privacy standards preempt all related state law. A single set of nationally applicable rules on medical information privacy is a critical next step to achieving the goals underlying HIPAA's privacy directive and, more generally, the shared goals of Congress, the Administration, and affected members of the private sector in ensuring the most effective means of protecting individually identifiable health information from unwarranted use and disclosure. Conversely, adding a new layer of federal regulation without fully preempting state privacy standards, as would occur under the Proposed Rule, will compound the difficulties of compliance for everyone. In the case of insurers, higher compliance costs resulting from additional complex regulatory requirements will almost certainly be passed on to consumers in the form of higher insurance premiums – a result contrary to HHS's fundamental mission of fostering affordable health care for the American public.

II. SPECIFIC COMMENTS

A. Definitions: Sections 160.103 and 164.504

1. Health Plan

The Proposed Rule directly applies only to "covered entities," including, as one of three types of entities, health plans. The Proposed Rule's definition of "health plan" could conceivably bring substantial amounts of a multi-line insurer's business within the scope of its application. The "health plan" definition is taken from HIPAA's administration simplification amendment to the Social Security Act. HHS comments in the preamble to the Proposed Rule (the "Preamble") indicate that the term "health plan" should be broadly construed to encompass any individual or group health plan that provides or pays for the cost of medical care.[4] The Proposed Rule also lists the same fifteen examples of health plans that are listed in the Social Security Act.

The Proposed Rule's listing of specific types of health plans is not exhaustive. Rather, it includes a "catchall" category including "any other individual plan or group health plan, or combination thereof, that provides or pays for the cost of medical care." HHS has sought comment on how this "catchall" category should be applied.[5] This request for comments highlights an ambiguity in the proposed definition of "health plan" that we strongly believe must be eliminated.

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4 Id.

5 64 Fed. Reg. at 59932.

In discussing the definition of "health plan" in the Preamble, HHS states that "[c]onsistent with the other parts of HIPAA, the provisions of this rule generally would not apply to certain types of insurance entities, such as workers' compensation and automobile insurance carriers, other property and casualty insurers, and certain forms of limited benefits coverage, even when such arrangements provide coverage for health care services."[6] The reference to "generally" in this statement suggests that there may be exceptions to the exclusion from the Proposed Rule of such "certain types of insurance entities." This suggestion is troubling, and creates considerable ambiguity regarding what is and what is not a "health plan." Further, the listing of examples of entities to which the Rule would not apply, while instructive, is not explicit to the extent that we believe warranted pursuant to HIPAA.

HIPAA expressly lists the benefits excepted from its scope, and that list is identical to the provision cited by HHS in this portion of the Preamble. See 42 U.S.C. § 300gg-91(c) (cited in the Preamble as 29 U.S.C. § 1186(c)).[7] Thus, it appears that the agency originally intended to implement Congress' intent to exclude from the Rule's application the HIPAA "excepted benefits." The Proposed Rule, however, does not accomplish this. We are particularly concerned in this context about disability income insurance and limited scope dental and vision coverage (as well as long-term care insurance, which the Proposed Rule – we believe erroneously, as discussed below – includes in the definition of "health plan"). Although not mentioned by name in the Preamble, disability income insurance is included along with workers' compensation insurance, automobile insurance, and other coverages (some of which may have secondary or incidental benefits for medical care), in the cited HIPAA "excepted benefits" list. For the same reason, the other "excepted benefits" products, such as limited scope dental and vision plans, should not be considered "health plans" subject to the Rule. These products are forms of limited benefits coverage that provide reimbursement only for certain limited health care services.

Also of great concern, the Proposed Rule expressly includes within the definition of "health plan" one of the HIPAA excepted benefits: a long-term care policy, "regardless of how comprehensive it is."[8] The inclusion of long-term care policies without exception appears flatly at odds with HIPAA, which lists long-term care "if offered separately" as one of the statutorily excepted benefits.' Moreover, such treatment of long-term care insurance as a "health plan" is contrary to HHS's explicit intent that the Rule not be applicable to certain forms of "limited benefits coverage."

Consistent with the distinction in HIPAA's portability requirements between group health plans providing medical care and those providing "excepted benefits" (e.g., disability income insurance, limited scope dental and vision plans, and long-term care),

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6 Id.

7 64 Fed. Reg. at 59932.

8 Id. at 59931.

9 42 U.S.C. § 300gg-91(c)(2)(B).

HHS should excluded such benefits from the Rule's scope. This would be fully consistent as well with HIPAA's administrative simplification requirements, pursuant to which the Secretary must consider whether particular long-term care policies are in the nature of comprehensive plans primarily providing or reimbursing medical care[10] or rather provide coverage that is of limited scope and therefore should not be treated as a "health plan." In this connection, we note that these products are extremely cost-sensitive. This means that should plans providing these products pass on regulatory implementation costs, such as those attendant to the Proposed Rule, to their customers, it would likely result in fewer individuals taking part in such plans and the diminution of availability of such limited scope plans.

Long-term care insurance that is not provided as part of a group health plan does not provide the type of coverage that would warrant its inclusion in the Rule's definition of "health plan." Long-term care insurance, unlike major medical insurance, does not focus on "medical care" – the "diagnosis, cure, mitigation, treatment or prevention of disease,"" but rather covers services that are largely custodial in nature. For example, long-term care insurance policies typically cover the costs of services to assist a person with a chronically disabling condition in performing basic life functions (bathing, dressing, feeding, etc.), cooking, shopping, household maintenance, transportation, and basic financial transactions. The policies may cover prescription drugs as well, but they do not primarily cover the costs of medical care. Given the nature of long-term care benefits, we strongly believe there is no justification for including stand-alone long-term care insurance within the definition of "health plan" in the Rule.

Even with respect to those types of insurance coverage that HHS has expressly stated it does not intend to regulate under the Rule, the Proposed Rule does not significantly provide for exclusion of these types of insurance from the Rule's scope. We are particularly concerned about the Rule's ambiguity with respect to regulation of disability income insurance, limited-scope dental and vision plans, and property-casualty insurance (including workers' compensation insurance).

To address these concerns, we recommend that the definition of "health plan" be amended to exclude all of the HIPAA excepted benefits. This could be accomplished by inserting the following sentence after the second sentence (before the sentence "'Health plan' includes the following, singly or in combination:"):

> Such term does not include any policy, plan or program providing, arranging, administering, sponsoring, supporting or coordinating any of the benefits (or any combination thereof) excepted under 42 U.S.C. § 300gg-91(c).

We also are concerned that the proposed definition of "health plan" could be interpreted to include any entity, whether a business or not-for-profit organization, that

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[10] HIPAA § 262(a)

[11] 42 U.S.C. § 2791(a)(2)(A) (Public Health Service Act).

provides health benefits to its employees under a health benefit plan, particularly if the plan is self-insured. Entities that provide medical services on site to their employees may also be directly subject to the Proposed Rule, as these entities could be viewed as meeting the definition of "health care provider." Application of the Proposed Rule in these instances could very significantly discourage employers from offering such benefits and medical services to their employees.

2. Payment

Under the Proposed Rule, disclosures and uses of protected health information would be permitted for purposes of "payment." Such authority is critical to ensure effective delivery of medical benefits under health and other types of insurance. We are concerned, however, that the proposed "payment" definition may be narrowly construed to exclude certain critical payment-related activities, particularly in two areas.

(i) Excepted benefits: It is critical that the Rule not interfere with the administration and delivery of HIPAA "excepted benefits," to the extent that covered entities must use or disclose protected health information in order for insurers to administer such benefits. Most obviously, health care providers must be protected from liability under the Proposed Rule for disclosing protected health information to, for example, a disability income or dental insurer. To clarify that the Rule would not create such liability, we propose adding a new paragraph at the end of the definition of "payment." Such new paragraph, to be designated as paragraph (2)(vi) of the definition, would read as follows:

> (vi) Determination of compensability, causal relationship or liability with respect to benefits excepted under 42 U.S.C. § 300gg-91(c).

(ii) Stop-Loss Insurance and Reinsurance. The proposed definition of "payment" also does not address the critical functions of stop-loss insurance and reinsurance. The financial security of health plans and health insurers generally depends upon stop-loss insurance and reinsurance that can only be made available through unrestricted access to all material health plan coverage, pricing and claims administration information.

Insurers provide stop-loss coverage policies issued to employer sponsors' health benefits plans. Stop-loss coverage indemnities an employer plan sponsor in the event that self-funded health claims exceed specified limits. Stop-loss benefits are paid only to the employer sponsor. The insurer does not pay any policy benefit to health plan participants or health care providers.

Reinsurers indemnify health insurers for portions of their insured health plan claims liabilities. The reinsured portion of an insurer's liability may be a percentage of each covered claim, an amount in excess of specified amounts of claims, or some other contractually defined amount. The reinsurer pays the reinsured portion of an insurer's

claims only to the ceding insurer. The reinsurer does not make any reinsurance payments to an individual policyholder, health plan participant or health care provider.

We recommend, therefore, that the definition of "payment" in the proposed rules be revised to include the specified functions of obtaining stop-loss insurance and ceding reinsurance. Specifically, we recommend amending paragraph (l)(i) of the definition to read as follows (proposed new language is italicized):

> (i) A health plan, or by a business partner acting on behalf of a health plan, *(a)* to obtain premiums ~~or~~ *for the health plan coverage; (b)* to determine or fulfill its responsibility for coverage ~~under the health plan~~ and for *the* provision of benefits under the health plan; *or (c) to obtain stop-loss insurance or to cede reinsurance of the health plan coverage;* or

B. Introduction to General Rules: Section 164.506

1. Special Categories of Protected Health Information

HHS has requested comment on whether the Proposed Rule should provide additional protection to protected health information which might be considered particularly sensitive.[12] In particular, with respect to protected health information dealing with genetic and hereditary or other sensitive conditions, HHS has questioned whether such information will be adequately protected by the Proposed Rule or if additional safeguards are needed. Until such time as Congress enacts legislation that, through a clear set of federal standards, preempts all state law on the issue, we do not believe that additional requirements should be mandated for information relating to such conditions. In many cases, such information already enjoys additional safeguards, for example, the federal regulatory safeguards for information related to drug abuse[13] and the state law safeguards for information relating to HIV testing.

2. Creation of De-identified Information

HHS has solicited comment regarding the usefulness of de-identified health information as opposed to protected health information. From our perspective as an insurer and employer, de-identified information is not particularly useful. It cannot be used as the bases for insurance applications, to support claims for insurance benefits, nor in connection with on-site employee medical services or applications for employment. Therefore, de-identified health information is not a substitute for the types of information required as part of the day-to-day business of insurance.

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12 **64** Fed. Reg. at 59939.

13 **See 42** C.F.R. Part 2.

C. Treatment. Payment. and Health Care Operations: Section 164.506

1. Right to Request Restrictions

HHS has sought comment on the proposed provision permitting individuals to request that a covered entity restrict uses and disclosures of protected health information for purposes of treatment, payment, or health care operations.[14] The agency has evaluated the benefits to individuals and the burdens of this proposed provision. The agency apparently has not, however, considered the adverse effect the proposed provision would have on insurance underwriting and claims payments, This adverse effect would negatively impact both covered entities and insurers that are not covered entities under the Proposed Rule.

An agreement by a covered entity-in particular, a health care provider-not to disclose an individual's protected health information for health care treatment and payment purposes could significantly undermine accurate evaluations of the insurability and claims eligibility of the individual. Under the Proposed Rule, insurers would have no way of knowing that, due to such agreement, the protected health information they receive from a provider constitutes an incomplete record of the medical condition of the individual. In reliance on such an incomplete record, insurers would make underwriting and claims coverage decisions contrary to their obligations under the insurance unfair discrimination laws of the various states. Under those laws, insurers are required to base their underwriting and claims coverage decisions on the risks associated with an applicant or policyholder and to treat similarly situated individuals in the same fashion. Absent adherence to this requirement, the insurance underwriting process is undermined by unfair distortions and adverse selection.

We propose two alternative amendments to the Proposed Rule to prevent this apparently unintended, adverse result. First, we propose deleting Section 164506(c)(l). Second, as a less preferable alternative, we propose adding a new paragraph (c)(1)(ii)(D) to read as follows:

> (D) To disclosures to an insurer pursuant to an authorization permitted under Subsection 164.508(a)(l).

2. Business Partners

The Proposed Rule broadly defines "business partner" as "a person to whom the covered entity discloses protected health information so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the covered entity." HHS proposes to ensure compliance on the part of business partners by requiring covered entities to develop contracts with their partners and by holding the covered entities responsible for ensuring compliance. MetLife respects and shares with HHS the desire to be as protective of individuals' health information as possible. We

[14] Id. at 59946.

also commend the agency for its stated desire to achieve this while allowing customary business relationships in the industry to continue." The Proposed Rule would, however, in fact alter those business relationships significantly, indeed drastically in some instances, We object to being held liable for others' unauthorized acts and seriously question whether the Proposed Rule's provisions regarding business partners would achieve HHS's goals.

The Proposed Rule does recognize the need for covered entities to disclose individually identifiable information to the types of persons and entities included in its definition of "business partner." However, the Proposed Rule contains a fundamentally unworkable requirement: that covered entities may disclose protected health information to business partners only pursuant to contracts with those partners, or under one of a few other provisions (under section 164.508 pursuant to an authorization, under section 164.5 10 where specifically permitted, under section 164.5 14 upon request of the individual, or under section 164.522 as required by the Secretary to conduct investigations). The business partner contracting requirement, if adopted as proposed, will have a substantial adverse impact on existing contractual and other arrangements. Where contracts are already in place between covered entities and their business partners, amendments to those contracts (or, in some cases, new contracts) will be required. The proposed contracting requirement will likely have the effect of substantially lengthening and complicating the contracting process, increasing the cost of doing business on both the covered entities and business partners, and ultimately making health care less efficient and/or more costly for consumers.

The Proposed Rule would prohibit disclosure by a covered entity of protected health information to a business partner "without satisfactory assurance from the business partner that it will appropriately safeguard the information." "Satisfactory assurance" is defined to mean the execution of a contract that contains several specific provisions, including:

(i) a requirement that the business partner "report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;"

(ii) a requirement that the business partner return or destroy all protected health information received from the covered entity;

(iii) a requirement that "the individuals whose protected health information is disclosed under the contract are intended third party beneficiaries of the contract;" and

(iv) a requirement that a material breach by a business partner of its obligations under the contract be considered noncompliance of the covered entity, if the covered entity knew or reasonably should

[15] 64 Fed. Reg at 59947.

have known of such breach and failed to take reasonable steps to cure the breach or terminate the contract.

The effect of the first of these requirements (the reporting requirements) would be to force a "communication" that a contract has been breached and/or a regulation violated. This would appear to require an entity to, in essence, admit it has breached its contract.[16] Businesses will resist any provision that forces such an admission.

The second requirement (regarding return or destruction of information) is contrary to a number of established insurance business practices. Standard insurance industry third-party agreements do not generally permit the disclosure of any confidential information without the insurer's consent or require the return of such information. There are instances, however, where accounting and auditing firms are required to retain certain information in order to meet professional obligations. In addition, if a contract has a lengthy term, and the business partner has the protected health information in computerized form, the business partner will likely have backed up the information multiple times. It is not realistic to assume that the vendor will go through all backup media in order to delete this information. In such cases, the firms are usually required to maintain the confidentiality of any data in accordance with the agreement, even after termination of the agreement.

The third requirement (making individuals third-party beneficiaries) raises other serious issues. Most parties enter into agreements for purposes of certainty. By adding thousands – or perhaps millions – of unknown third-party beneficiaries, this proposed requirement could expose insurers to unwarranted liability, and spawn a whole new class of litigation. In addition, the parties may become very uneasy and less likely to enter into an agreement where unknown third parties can without warning sue for a claim of breach. Contracts also frequently contain proprietary and/or trade secret information that the parties will be unwilling to share with these unnamed third-party beneficiaries for fear of losing their state or federally protected intellectual property rights. Allowing individuals to have unlimited access to business partner contracts could therefore also jeopardize trade secret law rights. At the very least, we believe that a more narrow provision allowing third-party beneficiaries access only to the contract's confidentiality requirements would achieve HHS's goals without giving rise to potential new litigation or creating an undue burden on the contracting process.

The fourth requirement (holding covered entities liable for acts of business partners) also causes us great concern. Although, under agency law, the principal is usually liable for acts done by its agent within the scope of the agent's authority, a typical contract makes each party responsible for its own actions. The proposed requirement making a principal liable for an agent's acts beyond the scope of the agent's authority is inequitable, as well as contrary to current business practices and a long line of American judicial decisions.

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[16] It also would potentially require the entity to waive its Fifth Amendment rights if there are criminal sanctions involved.

Further, by making the covered entity essentially the "keeper" of the business partner, it will be in the covered entity's interest to create a contract with very high standards for the business partner's liability. Business partners may be unwilling to sign such broad liability provisions, leaving the covered entity with a choice of agreeing to a lower liability standard for the business partner and assuming more of the liability itself for the acts of an unaffiliated third party, or performing the service itself when it had already determined that the more cost-efficient alternative was to have a third party perform the service. Alternatively, the business partner may agree to accept such liability only in exchange for a higher fee. In addition, many covered entities may feel the need to provide for comprehensive and frequent audits of their business partners to determine compliance with the agreement, increasing the cost of doing business on both parties.

The suggested remedies could create additional problems. For example, if a third-party vendor breached its agreement, termination of the contract is not an appropriate remedy. Terminating the agreement might well cause the insurer to breach its obligations under the insurance policies and perhaps even violate numerous state insurance laws.

In light of all these concerns, we recommend that the business partner provisions of the Proposed Rule be deleted in their entirety. If, however, contrary to our recommendation, the business partner concept is retained in the final Rule, we strongly believe that a covered entity should only be held responsible for its own acts and not for the acts of its business partners. We recommend the following specific changes to Section 164.506(e) in order to limit a covered entity's liability for the acts of its business partners:

In Section 164.506(e), amend subsections (1) and (2) as follows (proposed new language is italicized):

- Amend paragraph (ii) of subsection (1) to read:

  (l)(ii) A covered entity must take reasonable steps to *advise its business partners of* ~~to ensure that each business partner complies with~~ the requirements of this subpart .

- Add a new paragraph (iii) to subsection (1) stating:

  (iii) A covered entity may rely in goodfaith on the business partner to carry out such partner's responsibilities under the contract required by paragraph (e)(2)(1) of this section.

- Delete from paragraph (iii) of subsection (2) the words "or reasonably should have known."

3. Minimum Necessary

As indicated above, the quality and quantity of information available to an insurer regarding insurance applicants or policyholders is a critical determinant of whether the insurer will be able to properly underwrite policies and to effectively evaluate and process claims. We are very concerned that under Section 164.506(b)(l) of the Proposed Rule, which provides that the covered entity must "make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure, " insurers would be deprived of key information needed to make accurate underwriting and benefit claims determinations. The extent of discretion afforded to the covered entity by the proposed "minimum necessary standard" standard, even where the individual has provided an authorization, is inappropriate in the insurance context, Proposed Section 164.506(b)(1) requires a covered entity, upon receiving an authorization for disclosure of protected health information, to exercise judgment as to how much information the intended recipient needs. Because Section 164.506(b)(1) directs the covered entity to provide as little information as possible, it is likely to result in less information being disclosed for underwriting and claims purposes, and less reliable information being disclosed.

This could have serious adverse effects on proper insurance activities, including underwriting. For example, a life insurer (a noncovered entity) regularly obtains from individuals authorizations for disclosures by their physicians of individually identifiable health information in order for the insurer to determine the individual's eligibility for a policy. Physicians are not in the business of underwriting life insurance, and should not be expected to have to educate themselves to become sufficient experts to judge what health information is or is not necessary for underwriting purposes. But, under the proposed Section 164.506(b)(1), physicians would have to make such judgments in an effort to avoid liability for having disclosed more information than might be deemed "minimally necessary." Given the penalties they would face should a disclosure be deemed by HHS not to have been absolutely necessary, physicians will likely err in the direction of nondisclosure, thereby impeding accurate insurance determinations.

To address this problem, we propose amending Section 164.506(b)(l) to enable covered entities, when they have received an individual authorization for disclosure of protected health information to specific persons or entities for a specified purpose, to rely on those persons or entities' representations regarding the scope of information needed for the purposes of the authorized disclosure. Specifically, we recommend that Section 164.506(b)(3) ("Implementation Specification: Reliance") be revised as follows:

After the words "not required by other law," add the italicized language below so that the remainder of the subsection reads:

> *"orpursuant to an authorization by the individualfor disclosure to a specified third party for a specified purpose orpurposes,* a covered entity may reasonably rely on the representation of such officials *or specified thirdparty* that

the information requested is the minimum necessary for the stated purpose(s)."

4. Deceased Persons

Under Section 164.506(f) of the Proposed Rule, information that is "protected health information" as defined in the Rule would remain such for two years after the death of the subject of the information. This standard would likely have a significant adverse effect on the payment of life insurance benefits, despite the fact that life insurers are not "covered entities" under the Proposed Rule. This is one of numerous aspects of the Proposed Rule that, contrary to HHS's intention, would interfere with the business activities of insurers that are not "covered entities" under the Rule.

When a life insurance policyholder dies, the policy beneficiary may be required to submit information regarding the decedent's health to support his or her claim. However, a beneficiary, such as a fiancee or friend, may be unable to obtain the authorization required to release information to the insurer, particularly if, for example, the decedent's estate does not require probate or if the beneficiary is not on good terms with the decedent's next of kin. Similarly, a beneficiary such as a charity would also be likely to encounter difficulty obtaining such an authorization, as it would have no legal standing with respect to the decedent or the decedent's estate. Particularly in cases where the policyholder dies within two years of the policy's issuance (i.e., within the policy's contestable period) and the cause of death is uncertain, the insurer's inability to access relevant protected health information would significantly interfere with claim payments and increase administrative costs.

To correct this apparently unintended adverse effect of proposed Section 164.506(f), we propose that the provision be amended to permit the beneficiary or payee under a life insurance policy to authorize disclosure of protected health information pertaining to the cause of death of a decedent policyholder. Specifically, we recommend that the final sentence of Section 164.506(f) be amended to read as follows (proposed new language is italicized):

> (f) . This requirement does not apply to uses or disclosures for research purposes, *or to disclosures to a provider of life insurance benefits where the beneficiary or payee of a life insurance policy authorizes disclosure of protected health information relevant to a determination of the cause of death of the life insurance policyholder.*

D. Individual Authorization: Section 164.508

1. Requests by Covered Entities

Section 164.508(a)(2)(ii) of the Proposed Rule would require a covered entity to request and obtain an authorization from the individual in order to use or disclose protected health information in a variety of circumstances, including "use and disclosure to non-health related divisions of the covered entity, e.g., for use in marketing life or

casualty insurance or banking services." (Section 164.508(a)(2)(ii)(C).) It is not clear what the term "division" refers to in this provision. The term appears to mean an entity outside the covered entity, rather than a subset *within* the covered entity, in part because the separate, preceding Section 164.508(a)(2)(ii)(A) requires an individual authorization for use of protected health information "for marketing by the covered entity." Further, the Preamble explains that this section of the Proposed Rule is intended to cover situations such as when a covered entity seeks an individual's authorization to disclose protected health information "to a *subsidiary* to market life insurance to the individual.""

We understand HHS's concern regarding disclosures of protected health information to affiliates of covered entities for non-health-related purposes, as reflected in the Preamble. [18] The Proposed Rule, however, fails to articulate a standard that clearly addresses this concern. To clarify the intended application of Section 164.508(a)(2)(ii)(C), i.e., that it applies to disclosures to entities outside the covered entity, we propose that paragraph (C) be amended to read as follows (proposed new language is italicized):

> (C) ~~Use and~~ Disclosure to non-health related ~~divisions~~ *affiliates* of the covered entity~~, e.g.,~~ for ~~use in~~ marketing ~~life or casualty insurance or banking services~~ *purposes.*

We believe the elimination of the "e.g." phrase in this paragraph eliminates confusion and is consistent with HHS's intent, given that Section 164.508(a)(2)(ii)(C) itself is one example of the circumstances that, under Section 164.508(a)(2)(i), require an individual authorization.

2. Form and Content of Authorizations

Subsections 164.508(c) and 164.508(d) require that an authorization identify, among other things, (i) the information to be used or disclosed in a "specific and meaningful fashion," (ii) the covered entity which is being authorized to make the disclosure, and (iii) the person or entity to which disclosure may be made. The authorization also must contain the individual's signature, the date of execution and an expiration date, as well as a statement acknowledging that the individual may revoke the authorization and an acknowledgment that, depending the status of the person or entity to whom the information is provided, such information may no longer be protected.

In the insurance industry, authorizations are generally included as part of application forms for underwriting purposes, or as part of claim forms. These authorizations are "standard" forms signed at the time an application or claim form is signed and submitted to the insurer. A typical authorization will authorize "any medical

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[17] 64 Fed. Reg. at 59952 (emphasis added)

[18] The Preamble explains that the uses and disclosures to which Section 164.508(a)(2)(ii) applies are uses and disclosures "for purposes outside of treatment, payment, or health care operations." Id.

practitioner or facility, insurer, consumer reporting agency or the Medical Information Bureau to provide the insurer with "medical data," including information related to "mental illness, sexually transmitted diseases, or test results." The authorization language is fairly broad because, until the application or claim is actually received and reviewed, an insurer cannot determine what information, if any, it will require to process the transaction.

The requirement in Section 164.508(c)(1)(i) that the information to be disclosed be identified in a "specific" fashion could substantially delay the issuance of policies and payment of claims. We therefore recommend that the words "specific and" be deleted from this paragraph and that the term "class of information" be added, so that the paragraph will more appropriately read as follows (proposed new language is italicized):

> (i) A description of the information to be used or disclosed that identities the information *or class of information* in a ~~specific and~~ meaningful fashion;

We also have concerns about certain aspects of Subsection (d) of Section 164.508. First, we believe paragraph (d)(l)(i), which requires that the authorization contain a statement that neither treatment nor payment is conditioned on the individual's providing authorization, must be modified in order to permit normal insurance claims processing. A health insurance claim generally cannot be paid without sufficient documentation, including a description or other identification of the service rendered, the date of and physician's charge for the service and the diagnosis. If the covered individual does not provide this information to the insurer or health plan administrator in an acceptable form (such as an original receipt from the physician containing the required information) or authorize the physician or other medical service provider to disclose it, the claim can not be processed and paid (or denied). We therefore recommend that the words "or payment" be deleted from Section 164.508(d)(l)(i).

Second, we also object to paragraph (d)(1)(iv), which requires that, "[w]here use or disclosure of the requested information will result in financial gain to the entity," a statement to that effect must also be included in the authorization. We do not understand the purpose of this requirement. Health insurance is a business. As such, the insurer must receive adequate premiums to cover claims and expenses, to fund required reserves, as well as to provide a profit margin, On that basis, we object to this requirement and recommend that it be deleted.

Finally, we are concerned that, if these regulations are adopted as currently drafted, we would not be permitted to use a single authorization form but be required to have multiple authorization forms, As noted above with respect to underwritten individual insurance policies, the authorization generally is incorporated into the application form that is tiled with the state insurance departments, The authorization permits the insurer to obtain information from many sources, e.g., consumer reporting agencies, motor vehicle departments, and employers, as well as from medical practitioners and facilities. The same form may authorize the insurer to redisclose information to the Medical Information Bureau, to reinsurers, and to affiliated companies

or contractors performing business services with respect to the insurance. If the regulations are adopted as drafted, insurers would be required to revise their authorization forms and to refile their application forms with the state insurance departments to obtain their approvals. Similarly, changes would have to be made to authorizations contained in claim forms, although those would not require refiling.

To address this concern, we suggest that Section 164.508 be amended to include a provision stating that the form may incorporate authorizations for the release and use of other types of information as well.

E. Uses and Disclosures Permitted Without Individual Authorization: Section 164.510

1. Law Enforcement

HHS clearly recognizes the importance of efforts by both governmental authorities and health plans and health care providers to prevent fraud in the health care area. However, the Proposed Rule, as currently drafted, would hinder insurers' access to medical information for purposes of detection and prevention of insurance fraud, quite contrary to HHS's antifraud policies.

Insurance fraud is primarily regulated at the state level." In 1995, the National Association of Insurance Commissioners ("NAIC") adopted the Insurance Fraud Prevention Model Act (the "Model Fraud Act"). The Model Fraud Act defines insurance fraud broadly to relate not only to claims, but to underwriting and other types of activities as well. Furthermore, it requires that any "person engaged in the business of insurance having knowledge or a reasonable belief that a fraudulent act is being, will be or has been committed" make a report to and provide supporting information to the insurance commissioner. Persons not in the business of insurance are permitted to make such reports and provide such information. In either case, the Model Fraud Act also provides that, as long as such reports and information supporting that belief are provided in good faith as prescribed, no reporting entity shall have civil liability as a result of and no cause of action shall arise from the report and related disclosure of information.[20]

The Proposed Rule would significantly undermine the reporting requirements of the Model Fraud Act, because the proposed "fraud" exception provided in Section 164.510(f) is much too restrictive. It permits reports to be made only in response to narrowly drawn requests, only in the case of health care fraud, and only when the entity believes in good faith that the information constitutes evidence of criminal conduct. This restrictive approach will severely limit investigations of insurance fraud by

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[19] Although the Violent Crime Control and Laws Enforcement Act of 1994 made it a federal act to "defraud, loot or plunder an insurance company," insurance fraud is generally defined as a crime under state criminal law or a violation of state insurance law.

[20] Currently, 3 1 states have statutes requiring or permitting such reports to be made and related information to be disclosed.

state insurance departments and enforcement agencies, denying them the information needed to identify and prosecute fraudulent insurance activities. In many instances, the reports and information provided by insurers reveal fraudulent activities that would not otherwise have come to the notice of regulators and law enforcement officials and into which no investigations would otherwise have been undertaken.

Insurance fraud has been cited as one of the main causes underlying the high cost of health care in the United States. The active investigation of suspected insurance fraud and the prosecution of those who commit insurance fraud have been cited as checks on the increasing costs of health care, workers' compensation and even auto insurance in recent years. President Clinton has proposed to increase the HHS budget for Medicare fraud investigation, and HHS even provides awards for reporting of Medicare fraud or abuse.*' The Proposed Rule, however, would undermine these and similar efforts dramatically, with insufficient potential gain to privacy.

Of even greater concern, the Proposed Rule could actually encourage and prevent the detection of insurance baud. As noted earlier, the Proposed Rule would likely result in less information being disclosed to insurers for underwriting and claims purposes, and less reliable information being disclosed. The perils are evident. Doctors and hospitals, which are not necessarily as sympathetic to insurers as to their patients, may edit portions of the medical file to remove documents or information that might prevent their patient from obtaining coverage or receiving a claims payment. Under the Proposed Rule, health care providers would have an affirmative right, if not a duty, to edit the information provided, without any guidelines as to what is necessary to accomplish the intended purpose of the disclosure. The adverse impact of this would not be limited to health insurance fraud. One could easily see how disability income insurance fraud, for example, could also be facilitated by these proposed changes in the law.[22]

To address these issues, the Proposed Rule's list of permitted disclosures for purposes of fraud detection and prevention should be expanded and clarified. Specifically, we recommend amending paragraph (f) of Section 164.510 as follows:

. in the lead-in sentence of paragraph (f), between the words "official" and "if," insert the phrase: "or in the case of fraud or suspected fraud under paragraph (f)(5) of this section";

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[21] See 42 C.F.R. § 420.400.

[22] For example, one of the most alarming trends facing the life insurance industry is a notable increase of a particular kind of fraud, referred to a "clean sheeting." Uninsurable individuals obtain life insurance policies by providing incorrect and misleading medical information on their applications for insurance. Once the policy is issued, the individual proceeds to "wet ink," or assign, the policy to a viatical settlement or similar company for payment of a percentage of the death benefit. In order to investigate these types of activities, insurers must be able to obtain and share information, among insurers and with state insurance and securities regulators. A direct and adverse consequence of these proposed regulations would be to encourage exactly this kind of criminal activity.

- in the lead-in sentence of paragraph (f)(5), after "criminal conduct," add the following:

> or the covered entity is responding to a request by a non-covered entity engaged in a good-faith investigation of suspected fraud or misrepresentation with respect to benefits claims where personal medical condition or history is material.

2. Disclosures for Banking and Payment Processes – Stop-Loss Insurance and Reinsurance

As discussed above in section B concerning the definition of "payment," the Proposed Rule does not address the critical functions of stop-loss insurance and reinsurance, which have an integral role in the provision of insurance benefits. Unrestricted access to all information material to health plan coverage, pricing and claims administration is essential to permit stop-loss insurance and reinsurance to function effectively. In order to ensure that the Proposed Rule does not apply to these critical insurance coverages, which are directly subject to privacy regulation under state insurance law, we recommend amending Subsection 164.510(i) as follows:

- in the title of subsection (i), insert "or stop-loss insurance or reinsurance" between "payment" and "processes"

- add a new paragraph (i)(3) to read as follows:

> (3) *Stop-loss insurers or reinsurers.* An entity engaged in the business of stop-loss insurance or reinsurance, where the disclosure is for the purpose of underwriting, pricing, determining coverage or administration of claims with respect to stop-loss insurance or reinsurance.

F. Notice of Information Practices: 164.512

The Proposed Rule would require covered entities that are either health plans or health care providers to provide a comprehensive notice to each individual who is the subject of a covered entity's protected health information. The notice must include language stating, among other things, the covered entity's policies and procedures with respect to uses and disclosures of protected health information; the individual's rights regarding uses, disclosure and access to such information; the name and telephone number of a contact person or office within the covered entity responsible for administering compliance with the regulations; and numerous other statements of great detail.

In addition to the comprehensive content of the required notice, the Proposed Rule mandates that a health plan provide a copy of the notice to every individual covered by the health plan at the time the Rule becomes effective, at the time of all enrollments in

the plan after the effective date, and at least once every three years thereafter. The notice must also be sent to an individual upon request and within 60 days after any material revision to the notice.

These notice and delivery requirements will impose particular hardship on group insurers and their customers in those group insurance plan arrangements in which the group policyholder maintains and controls the census of employee certificateholders. In these situations, the insurer does not possess the names and addresses of covered employees required for sending the notice. In addition, for many group insurance products, no individual underwriting is performed and no health information is collected at the time of enrollment. Accordingly, it does not make sense to require a notice for policyholders covered by these products, and to do so could create an enormous administrative burden.

The confusion created by an additional privacy notice is not likely to be of assistance to consumers. Existing state and federal laws already require insurers to provide privacy notices to insurance consumers.

The Insurance Information and Privacy Protection Model Act adopted by the NAIC ("Model Privacy Act") requires that privacy notices be delivered to applicants or policyholders in connection with most insurance transactions. Depending on the context within which personal information is being collected, the notice must be provided either at the time the information is collected or upon delivery of a policy or certificate. However, the Model Privacy Act recognizes that it makes little sense to require a notice in the case of group insurance products that are not individually underwritten. Thus, it does not require notice in these circumstances.

The privacy provisions of the recently enacted federal Financial Services Modernization Act[23] require all financial institutions (including insurers) to provide consumers with notices regarding the institution's policies and practices with respect to its disclosure and protection of consumers' nonpublic personal information. The required notices must disclose the categories of persons to whom information may be disclosed, the categories of information collected by the institution, and the policies in place by the institution to protect the confidentiality and security of nonpublic personal information. The statute's implementing regulations will detail the substance of these notice requirements.

Given the ambiguities of state law preemption under the Proposed Rule with respect to state notice requirements and the uncertainty of the content of the regulations forthcoming under the Financial Services Modernization Act, the Proposed Rule should not impose additional notice requirements. We believe that, quite contrary to HHS's intent, consumers will only be confused and frustrated by the multiple notices that would result from the Proposed Rule's notice requirements. If there is to be a notice requirement under the Rule, an exception should be made for group insurance contracts.

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[23] Pub. L. No. 106-102, Title V (1999).

Further, notices should only be required to be sent out when protected health information is actually gathered. Under no circumstances should subsequent notices be required unless the health plan materially changes its practices.

Many insurers already send their customers notices explaining their privacy policies. As a result of the Financial Services Modernization Act, these privacy notices will need to be revised and retransmitted. The Proposed Rule would require even farther changes and mandate insurers to repeatedly contact millions of current individual policyholders, providing different and perhaps even conflicting information each time. The result is likely to be customer confusion, not education. In addition, this will substantially increase insurers' administrative costs. We urge HHS to permit a more general notice and to attempt to resolve potential conflicts with other laws requiring similar notices as much as possible by permitting some latitude in the amount and type of information that must be provided.

G. Access for Inspection or Copying: Section 164.514

Information Compiledfor a Legal Proceeding. The Proposed Rule grants individuals a right of access to their protected health information, but would permit covered entities to deny an individual's request for access to protected health information that was compiled in reasonable anticipation of, or for use in, a "legal proceeding." The Proposed Rule does not define "legal proceeding." In order to clarify that Section 164.514 would permit disclosures in connection with the settlement of claims for medical and related benefits that may be disputed or challenged, we propose amending paragraph (b)(l)(v) of Section 164.514 by inserting between "for use in" and "a legal proceeding" the words "or in connection with a claim for benefits or."

H. Administrative Requirements: Section 164.518

As a general matter, we emphasize the extreme complexity and high costs that will be entailed in implementing the administrative requirements of the Proposed Rule. We urge that, in fashioning its final Rule, HHS make every possible effort to reduce the burdens on covered entities that these requirements will impose. We specifically note that for covered entities that are insurers, the costs of these requirements will inevitably be felt by consumers in the form of higher insurance premiums.

Training. HHS has requested comments on the propriety of requiring covered entities to have each member of the workforce sign a new statement every three years certifying that he or she will continue to honor the entity's privacy policies and procedures.[24] We believe that there are less burdensome methods that HHS could require to serve the purposes of recertification. For example, a covered entity could provide a notice electronically to all affected employees reminding them of this duty. This notice could actually be provided on a more frequent basis than every three years. The key is to afford covered entities the flexibility of not requiting a signed statement for

[24] **64** Fed. Reg. at 59989.

recertification situations. We believe that such flexibility would actually encourage covered entities to take a more active role in the retraining process.

HHS has also sought comment on whether its proposed requirement that retraining be provided by a covered entity in the event of material changes in the entity's privacy policy, but not otherwise, is sufficiently protective of individuals' privacy.[25] We believe HHS has appropriately determined that, given the proposed requirement for recertification by employees, a routine retraining requirement would impose burdens far in excess of the potential benefits to individual privacy.

I. Relationship Other Laws

1. Relationship to State Laws

The Proposed Rule provides for a general preemption of state law only to the extent that a provision of state law is "contrary" to the Rule, i.e., would be an obstacle to achieving the objectives of HIPAA. Insurers would still need to comply with state privacy laws, provided those laws are simply more restrictive than the requirements imposed by the regulations. Insurers would also be required to comply with other state laws that may be deemed contrary if the state law, for example:

- required disclosure by health plans for the purpose of financial or management audits,
- required disclosure for the purpose of reporting child abuse,
- is more stringent than federal standards, or
- is determined to be necessary by HHS to prevent, among others: baud.

In the last instance, if a state makes a determination that a provision of state law is "contrary" to the federal standard, it may apply to HHS to except the provision from preemption. Any preemption granted cannot exceed three years. This is not particularly helpful. Different states with similar provisions in their statutes dealing with privacy of health information may come to different conclusions as to whether those provisions are contrary to federal law. Even within a state, different state agencies may come to different conclusions. Insurers and other business entities will have difficulty gaining access to these internal state government decisions. Similarly, even in the case of laws determined to be contrary to the federal standard, an insurer would be unlikely to know if a state had requested an exception and, if so, whether the exception had been granted or not. Compliance will be extremely difficult.

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[25] Id.

As noted above, the NAIC has adopted a Model Privacy Act. Fifteen states have enacted laws substantially similar to the NAIC Model Privacy Act[26] and four states have related laws.[27] However, many insurers, such as MetLife, adopted their principles as corporate policy in all states. The Model Privacy Act imposes a number of conditions and limitations on the disclosure and use of personal and privileged information[28] relating to natural persons. For example:

- Section 13.L permits disclosure of such information to an affiliate "whose only use of the information will be in connection with the marketing of an insurance product, provided the affiliate agrees not to disclose the information for any other propose or to unaffiliated persons."

- Section 13.B also permits disclosure of personal information to an insurance institution, self-insurer or agent if reasonably necessary to permit such institution, self-insurer or agent "to perform its function in connection with an insurance transaction involving the individual."[29] This section clearly permits disclosure of personal and privileged information as necessary to, for example, process an application for insurance or claim for benefits. It also permits disclosure related to providing service with respect to an existing policy or contract.

As stated in our General Comments above, a federal privacy law fully preempting state and local laws in the area is preferred. Under the Proposed Rule, it is not clear whether state laws based on the Model Privacy Act would be preempted outright or be preempted partially, leaving only more restrictive provisions to be applied in addition to those imposed by the proposed regulations.

Given the confusion that will be generated by the ambiguity of whether particular state law provisions are "more stringent" than the Proposed Rule, we believe that

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[26] Arizona, California, Connecticut, Georgia, Illinois, Kansas, Massachusetts, Minnesota, Montana, Nevada, New Jersey, North Carolina, Ohio, Oregon and Virginia have enacted laws substantially similar to the NAIC Model Act.

[27] New York, Maine, Rhode Island and Wyoming have related laws.

[28] "Personal information" means any individually identifiable information gathered in connection with an insurance transaction. It includes medical and financial information as well as the individual's name and address. "Personal Information" does not include "privileged information." Privileged information is defined as individually identifiable information that relates to or is collected in connection with a claim for benefits. However, disclosure of personal information and privileged information is generally subject to the same limitations and conditions.

[29] Au "insurance transaction" is a transaction that involves the determination of an individual's eligibility for insurance coverage or the servicing of an insurance application, policy, contract or certificate.

guidance from the Secretary with respect to state law preemption should be available not only at the request of the states, but also at the request of those entities most directly impacted by the Rule-the covered entities. We also believe the requested guidance should be provided in all circumstances, not only at the Secretary's discretion. We therefore strongly urge HHS to amend Section 160.204(b) ("Advisory opinions") as follows:

- Revise the second sentence of paragraph (1) to read as follows (proposed new language italicized): "The Secretary ~~may~~ *shall* issue such opinions at the request of a State or *covered entity* or at the Secretary's own initiative.

- In the introductory phrase in paragraph (2), insert "or a covered entity" between "A state" and "may submit."

- In paragraphs (2)(i), (ii), and (iii), replace the word "exception" with the word "opinion."

- In paragraph (2)(iv), insert "or should" between "why the State law should" and "not be preempted."

2. Relationship to Other Federal Laws

At the federal level, there are also conflicts that must be resolved between the Proposed Rule and regulations dealing with, for example, Medicare fraud reporting and rules relating to federally funded alcohol and drug programs.[30] There are also potential conflicts with pending or enacted laws. Pending disability rules under the Occupational Safety and Health Act should be considered. Another example, as discussed above, is how the Rule will be reconciled with the privacy provisions of the recently enacted Financial Services Modernization Act and its implementing regulations.

The contact person for these comments is:

Martha Nolan
Senior Washington Counsel
Metropolitan Life Insurance Company
Suite 800
1620 L Street, N.W.
Washington, D.C. 20036
202-659-3575

[30] See *42* C.F.R. Part 2.